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Submission of Priority Document

The Examiner has acknowledged receipt of papers submitted under 35 U.S.C. 119(a)-(d), which have been made of record in the file. In order to perfect priority, as well as to comply with the Examiner's request, Applicants hereby attach an English translation of the application as **Exhibit A**.

Remarks

Claims 1-6 are pending in this application.

By the Amendment, Applicants amended claims 1 and 4 as suggested by the Examiner in the June 28, 2004 Office Action. Applicants also presented new claims 7-20. Support for the claimed elements can be found in the Specification as originally filed, e.g.:

- (a) "adding an appropriate amount of acid or base to precipitate the protein from the whey stock solution", e.g., see page 9, lines 14-16.
- (b) "separating proteins from the whey stock solution to obtain a supernatant", e.g., see page 9, lines 16-18.
- (c) "pasteurizing the supernatant", e.g., see page 9, lines 18-20.
- (d) "selecting a mushroom mycelia with optimal growth rates in the supernatant", e.g. see page 10, lines 4-18.
- (e) "inoculating the supernatant", e.g. page 11, lines 12-17 and page 12, lines 1-6.

Accordingly, there is no issue of new matters and Applicants respectfully request the entry of this Amendment. Upon entry of this Amendment, claims 1-20 will be pending and under examination.

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35 U.S.C. §112 - Claim Rejections (First and Second
Paragraphs)

The Examiner rejected claims 1-6 under 35 U.S.C. §112, first paragraph, as based on a disclosure which is not enabling. Examiner stated "the step of placing the aerobically culturing mushroom mycelia critical or essential to the practice of the invention is not included in the claims (specifically claims 1 and 4)." Examiner further stated "claims 1 and 4 are drawn to growing mycelia in a reactor but not in a medium or solution which is not enabled by the disclosure."

The Examiner rejected claims 1-6 under 35 U.S.C. §112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. The Examiner stated "the omitted steps are: In claims 1 and 4, the steps of placing the mycelia in the medium then placing the medium/mycelia combination in the reactor."

In response, but without conceding the correctness of the Examiner's position and to expedite prosecution of this application, Applicants have amended claims 1 and 4, and added the step of "placing mushroom mycelia in the medium" as suggested by the Examiner. Accordingly, Applicants respectfully requests the reconsideration and withdrawal of the above grounds of rejection.

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35 U.S.C. §103 - Claim Rejections (Claims 1, 2, 4, and 5)

The Examiner rejected claims 1, 2, 4 and 5 under 35 U.S.C. §103(a) as being unpatentable over Keggins et al. (US 4,544,637) in view of JP62-278922.

Examiner stated:

As to claim 1, Keggins et al. discloses a method for treating whey (abstract) comprising the step of separating proteins (abstract) from a whey stock solution ("sweet whey" of abstract) to make a medium (for example, example 1 of col.8), adjusting the medium to pH 3.8-6 (col.9 lines 61-3) and growing organism (Table 9 of col. 10). Not disclosed is the organism being mushroom mycelia and placing in a reactor at 25-32 C. JP62-278922, however, discloses using a whey medium in growing mycelia (abstract in English) and it is old and notoriously well known to grow mushrooms in a reactor at between 25 and 32 C. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Keggins et al. by using with mushrooms as disclosed by JP62-278922 so as to use a medium which also uses discarded soybean lees so as recycle a waste product.

As to claim 2, the limitations of Claim 1 are disclosed as described above. Not disclosed is the reactor set at 28.3 C and pH of 4.2. It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the method of Keggins et al. as modified by JP62-278922 so as to optimize the reactor so as to achieve a particular growth rate with a particular mushroom species.

As to claim 4, Keggins et al. discloses a method of culturing and organism (abstract) comprising the step of separating proteins (abstract) from a whey stock solution ("sweet whey" of abstract) to make a medium (for example, example 1 of col. 8), adjusting the medium to pH 3.8-6 (col.9 lines 61-3) and growing an aerobic organism (Table 9 of col.10). Not disclosed is the organism being mushroom mycelia and placing in a reactor at 25-32 C. JP62-278922, however, discloses using a whey medium in growing

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mycelia (abstract in English) and it is old and notoriously well known to grow mushrooms in a reactor at between 25 and 32 C. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Keggins et al. by using with mushrooms as disclosed by JP62-278922 so as to use a medium which also uses discarded soybean lees so as recycle a waste product.

As to Claim 5, the limitations of Claim 4 are disclosed as described above. Not disclosed is the reactor set at 28.3C and Ph of 4.2. It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the method of Keggins et al. as modified by JP62-278922 so as to optimize the reactor so as to achieve a particular growth rate with a particular mushroom species.

In response, Applicants maintain that the present invention relates to a method for culturing mushroom mycelia in whey so that the whey can be biologically treated at a disposal rate of 90% or higher, and at the same time, the mushroom mycelia can be mass-produced without any discharge of environmentally unfriendly sludge. .

As defined by claims 1 and 4, the methods of the present invention: is characterized in that mushroom mycelia are cultured in whey at the temperature of 25~32°C and pH 3.8~4.6. Fig. 6 shows evidently that such condition is optimum for culturing mushroom mycelia in whey.

Keggins et al. possibly describes a process for treating protein-free sweet dairy whey permeates to form a microbiological culture medium. The process comprises the steps of raising the pH of a dairy whey lactose permeate having a pH below about 7 to pH 8-10 by the addition of Lewis base at which the dissolved solids precipitates; separating

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the supernatant from the resulting precipitate to form a microcrystalline solid phase; removing components having a molecular weight above about 100 kdal from the supernatant to form a lactose-rich supernatant; and drying the resultant supernatant to form a dry powder microbiological culture medium, which is useful in clinical diagnostic methods.

As described in the specification, Keggins et al. possibly discloses a method of treating whey to produce a bacteriological culture media useful in industrial and clinical microbiology, not to produce mushroom mycelia. In the process, whey is added with base for increasing the pH to 8-10, so that the dissolved solids may become insoluble and precipitate. Even though Keggins et al. teaches the use of whey as a culture medium, it neither describes nor suggests that the optimum condition for culturing mushroom mycelia in whey is the temperature of 25~32°C and pH 3.8~4.6. Accordingly, Keggins et al. neither anticipates nor renders obvious the present invention.

JP62-278922 relates to edible mushroom culturing medium produced from tofu (soy bean curd) lees. In the preparation of the medium, tofu lees is pressure-dehydrated with the pH adjusted to 3.5-5.5 to obtain dehydrated tofu lees. The medium contains 40 wt.% or more of the dehydrated tofu lees, with the pH adjusted for the culture of mushroom, that is, pH 4.0-7.0. It is described that in the pH adjustment of the tofu lees, lactic-fermented acidic whey liquid may be used.

JP62-278922 discloses a mushroom culturing medium produced from tofu lees, not from whey. In JP62-278922, acidic whey is mentioned as one of acidic solutions for adjusting the pH of the culture medium made from tofu lees. Furthermore, in the

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process of JP62-278922, edible mushroom is cultured in the medium produced from tofu lees at pH 4.0-7.0. That is, JP62-278922 neither describes nor suggests the use of whey in culturing mushroom mycelia and the optimum condition for culturing them in whey. Accordingly, JP62-278922 neither anticipates nor renders obvious the present invention.

As mentioned above, in the present invention, mushroom mycelia are cultured in whey at the temperature of 25~32°C and pH 3.8~4.6, which is taught by neither Keggins et al. nor JP62-278922. Even though the mushroom of JP62-278922 is cultured in the microbiological culture medium of Keggins et al., the optimum condition defined in the present invention cannot be anticipated and the effect of the present invention cannot be accomplished.

a. Disposal or removal rate of organic substances in whey

Furthermore, neither Keggins et al nor JP62-278922, alone or in combination, teaches optimizing the removal and disposal of organic substances in whey at a rate which is comparable to conventional methods, i.e., greater than 90%, and which is accomplished, for example, by pre-treating the whey solution, selecting the suitable mushroom mycelia and/or controlling the pH and temperature of the reactor.

b. Relying on common knowledge

The Examiner stated that "it is old and notoriously well known to grow mushrooms in a reactor at between 25 and 32 C."

In response, Applicants respectfully traverse the Examiner's above assertion.

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Ordinarily, there must be some form of evidence in the record to support an assertion of common knowledge. See *Lee*, 277 F.3d at 1344-45, 61 USPQ2d at 1434-35 (Fed. Cir. 2002); *Zurko*, 258 F.3d at 1386, 59 USPQ2d at 1697. If such notice is taken, the basis for such reasoning must be set forth explicitly. The examiner must provide specific factual findings predicated on sound technical and scientific reasoning to support his or her conclusion of common knowledge. See *Soli*, 317 F.2d at 946, 37 USPQ at 801; *Chevenard*, 139 F.2d at 713, 60 USPQ at 241. To adequately traverse such a finding, an applicant must specifically point out the supposed errors in the examiner's action, which would include stating why the noticed fact is not considered to be common knowledge or well-known in the art. If applicant adequately traverses the examiner's assertion of official notice, the examiner must provide documentary evidence in the next Office action if the rejection is to be maintained. See MPEP § 2144.03(B) and (C).

Applicants' undersigned attorney has performed a search using online search engine, i.e., google.com, is not able to find any reference which describe growing "mushrooms in a reactor at between 25 and 32 C" is well known in the art. Applicants respectfully request the Examiner to provide any reference to support the above assertion that growing "mushrooms in a reactor at between 25 and 32 C" is well known in the art.

c. pH of the medium

The Examiner alleged that the claim limitation reciting adjusting the medium to pH 3.8 to [4.6] was disclosed in col. 9, lines 61-3 of Keggins et al.

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Applicants respectfully traverse the Examiner's above assertion. Applicants contend that Keggin et al. teach away from Applicants' claimed invention. Keggin et al. disclose raising the pH level, preferably to pH 9, to maximize the yield of the precipitate, i.e., inhibitory components. However, Applicants claim recite culturing the mushroom mycelia in a reactor at pH 3.8-4.6 to maximize the yield of the mushroom mycelia or removal of organic substances from the whey.

Furthermore, Keggin et al. does not disclose the Applicants' claimed pH range because Keggin et al. tested different pH ranges to observe the appearance of the samples. A person of ordinary skill in the art would still be taught to use pH 9 to achieve optimal removal of the inhibitory components. Keggin et al. states "the inhibitory components are removed... by the addition of sufficient non-toxic Lewis base... to raise the pH... to about 8-10, preferably to about pH 9. This increase in the pH... results in precipitation... with maximal yield obtained at about pH 9." See col. 3 lines 33-46. Col. 9, lines 61-67 of Keggin et al. disclose adjusting the initial pH to between 4 and 11, found that before autoclaving, the appearance of the samples were similar.

Accordingly, Keggin et al. and JP62-278922, either alone or in combination, fail to teach or suggest the present invention.

35 U.S.C. §103 - Claim Rejections (Claims 3 and 6)

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The Examiner rejected claims 3 and 6 under 35 U.S.C §103(a) as being unpatentable over Keggins et al. (US 4,544,637) in view of JP62-278922 in further view of JP2000-201647.

Examiner stated:

As to claim 3, the limitations of Claim 1 are disclosed as described above. Not disclosed is the mushroom being *G. lucidum*. JP2000-201647, however, discloses growing *G. lucidum* on a medium. It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the method of Keggins et al. as modified by JP62-278922 by growing *G. lucidum* as disclosed by JP2000-201647 so as to have a useful foodstuff (see JP2000-201647 at abstract in English).

As to claim 6 the limitations of claim 4 are disclosed as described above. Not disclosed is the mushroom being *G. lucidum*. JP2000-201647, however, discloses growing *G. lucidum* on a medium. It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify of Keggins et al. as modified by JP62-278922 by growing *G. lucidum* as disclosed by JP2000-201647 so as to have a useful foodstuff (see JP2000-201647 at abstract in English).

In response, Applicants maintain that the JP2000-201647 is directed to edible mushroom composition obtained by cultivation of plural kinds of mushrooms on sterilized culture medium. As mushrooms, *Ganoderma lucidum*, *Agaricus blazei* Murill, *Grifola frondosa* and *Lentinus edodes* are disclosed.

Even though JP2000-201647 discloses several mushrooms, it is quite different from the present invention in terms of its object, constitution and effect.

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Furthermore, since Keggin et al. and JP62-278922 fails to negate the patentability of claims 1, 2, 4 and 5 as mentioned above, claims 3 and 6 (dependent claims of claims 1 and 4, respectively) are also patentable over Keggin et al. and JP62-278922, regardless of JP2000-201647.

CONCLUSION

In summary, Applicants believe that all grounds of rejections raised by the Examiner in the June 28, 2004 Office Action have been addressed, and therefore this application is in full compliance with all requirements. Accordingly, Applicants respectfully urge the Examiner to reconsider and withdraw all rejections in the June 28, 2004 Office Action and place this application in conditions for allowance.

If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

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No fee other than the ONE HUNDRED AND TEN DOLLARS (\$110.00) fee for one-month extension of time and the EIGHTY-EIGHT DOLLARS (\$88.00) for an additional independent claim is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is given to charge the amount of any such fee to Deposit Account No. 50-1891.

Respectfully submitted,

Albert Wai Kit Chan

I hereby certify that this paper is being deposited this date with the U.S. Postal Service with sufficient postage for first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

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